

### **Remarks**

Claims 2-7, 9, 14, 16, 17, 19, 20, 22-24, and 27 have been amended. Claims 25 and 26 have been cancelled. New claim 28 has been added. Claims 8 and 10-13 were cancelled in a previous Response(s). Claims 1-7, 9, 14-24, 27, and 28 are presented for the Examiner's review and consideration. Applicants believe the claim amendments and the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

#### **Claim Amendments**

It is noted that references to the application/specification made herein are meant only to represent examples of support for amendments and/or teachings of the application/specification (used in arguments responding to rejections of claims) and are not a comprehensive list of support. The amendments and/or referenced subject matter may be supported in other parts of the application/specification not mentioned.

No new matter has been added by the amendments to claims 2-7, 9, 14, 16, 17, 19, 20, 22-24, and 27 made herein. These claims have been amended only for consistency of language and to provide proper antecedent basis for all terms recited therein.

Claim 22 has also been amended to clarify that the pad does not require long-term application to the punctured section of skin and can be removed in a time period of about twenty minutes or less. This concept is supported in the specification as originally filed. For example, see paragraph [0029] of the published application; U.S. Patent Application Publication 2006/0142708 A1; hereinafter "published application."

No new matter has been added by the addition of claim 28 made herein. This claim has been added to clarify that the pad is placed in direct contact with the surface of the punctured skin such that the materials contained within the pad can directly contact the surface of the punctured skin but remain contained within the pad and therefore do not seep into the needle

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puncture wounds. This concept is supported in the specification as originally filed. For example, see paragraphs [0014] and [0029] of the published application.

Rejection under 35 U.S.C. §112, first paragraph

Claims 25 and 26 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. Specifically, the Examiner asserts that the specification does not give any guidance as to what is necessary to “encourage infection” as claimed and thus, one of ordinary skill in the art would not know what this entails.

Applicants respectfully disagree with the Examiner’s assertion. However, in order to advance prosecution, claims 25 and 26 have been cancelled herein. Thus, this rejection is now moot.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. §112, first paragraph.

Rejections under 35 USC §103(a)

Claims 1-5, 9, 14-18, and 21-27 were rejected under 35 U.S.C. §103(a) as being unpatentable over Malodobry (U.S. Patent Application Publication 2004/0111107 A1; hereinafter “Malodobry”) in view of Bogart et al. (U.S. Patent 5,271,943; hereinafter “Bogart”). Claims 25 and 26 have been cancelled, thus the rejection is now moot with regard to these claims.

Claims 6, 7, 19, and 20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Malodobry in view of Bogart and Garitano et al. (U.S. Patent Application Publication 2004/0158196 A1; hereinafter “Garitano”). For reasons set forth below, Applicants respectfully submit that both of these rejections should be withdrawn.

The references are described individually in order to clarify what each reference teaches. Thus, the individual presentation of the references is not, and should not be construed as, an attempt to argue the references separately.

### Malodobry

Malodobry discloses a method for scarless removal of tattoos (non-natural colored pigments) from human or animal skin. *See abstract and paragraph [0039].* The method includes passing one or more tools (needles), which have rough or sharp-edged surfaces, through a pigmented skin surface in a manner essentially perpendicular thereto. *See abstract and paragraphs [0042] and [0045].* The needles enter agglomerates of color pigments and mechanically destroy them by breaking up the fragments. An abrasive agent, *i.e.* quartz or diamond dust, may be used to enhance the mechanical destruction. *See abstract and paragraphs [0041]-[0047].* The smaller fragments of the agglomerates are eliminated by the natural healing process of the skin and the vitality of the cells is preserved. The pigments are shifted outwards for healthy skin to grow from beneath. *See paragraphs [0041]; [0048]; and [0049].* The method may also include application of skin irritants to skin surface and/or introduction of the skin irritants into the agglomerates before, during, or after the mechanical destruction. *See paragraph [0050].* The skin irritants encourage inflammation and/or provide fillers in the cells to delay wound healing. These irritants can be solid or liquid and may include table salt. *See paragraphs [0051] and [0052] and claim 1.*

### Bogart

Bogart discloses therapeutic gels for promoting the healing of wounds. The gels include water, sodium chloride, and a gelling agent and have a minimum yield point of about 800 poise and a maximum apparent viscosity of about 100,000 centipoise (cps). *See abstract and column 3, lines 10-18.* The viscous properties allow the gel to conform to the interstices of a wound when applied directly thereto and to remain in the wound and not flow out when the patient moves. No dressing is required. *See column 3, lines 36-43.* The ingredients of the gels are physiologically compatible with body tissue and do not interfere with the healing process. *See column 3, lines 60-68; column 4, lines 20-26; and column 7, line 55 to column 8, line 11.* Bogart also discloses methods for treating wounds using the described gels. *See column 1, lines 5-10;*

column 7, line 55 to column 8, line 11; and Example 2.

Garitano

Garitano discloses a device (and methods for using the device) for needleless administration of permanent makeup and tattoos. *See abstract and paragraph [0006].* In particular, the device relates to hypodermic injectors for use in delivering pigment or other substances to targeted layers of the skin. With use of this device, one is able to avoid needlestick injuries and reduce transmission of disease. *See abstract and paragraph [0016].* Material is delivered by accelerating compressed air and can be dispersed throughout a greater volume of tissue as compared to dispersion with a conventional needle. *See paragraphs [0016]; [0033] and [0034].* Garitano also contemplates removal of pigment using the described device, including methods involving injection of a removal solution and suction or drainage of the solution from the skin. *See paragraph [0023].*

Instant Invention

The instant invention, as currently claimed in independent claims 1 and 28, provides, *inter alia*, a method for the removal of pigments from a pigmented section of skin, for example removal of a tattoo. Generally, the method includes puncturing the skin and bandaging the skin. *See abstract and paragraphs [0001] and [0014] of the published application.* In the puncturing step, the skin is punctured in a pigmented section using a skin-puncturing device having at least one needle. The needle punctures the pigment-containing cells which liberates the pigments and cellular fluid. *See paragraphs [0014] and [0027].* The bandaging step includes bandaging the punctured area of skin with a pad adapted to absorb the liberated pigments and cellular fluids. This pad contains one or more materials capable of accelerating migration of the liberated pigments toward an outer layer of the skin such that they can be absorbed by the pad. One or more of the materials is a salt-based granular paste. *See paragraphs [0014]; [0027]; and [0028].* When bandaging, the pad is placed in direct contact with the surface of the punctured section of

skin. The materials contained within the pad have direct contact with the surface of the punctured skin, but remain contained within the pad and therefore do not seep into the puncture wounds in the skin made by the needles. *See paragraphs [0014] and [0029].*

### Argument

Applicants respectfully submit that the combination of Malodobry and Bogart does not obviate the invention, and furthermore submit that Garitano adds nothing to remedy the deficiencies of this combination such that a combination of Malodobry, Bogart, and Garitano would obviate the invention as currently claimed. The claimed invention encompasses a method for removing pigments from a pigmented section of skin wherein cells containing the pigments are first destroyed to liberate the pigments and cellular fluid. The pigmented skin is then covered with a pad including a salt-based granular paste. The salt-based granular paste accelerates the migration of the pigments/cellular fluid outward such that the pigments/cellular fluids are absorbed by the pad and thus quickly removed from the skin.

The Examiner's position is summarized as follows: Malodobry teaches removal of pigments from pigmented sections of skin and suggests the use of skin irritants to accelerate the process; Bogart teaches a method for applying a salt-based gel thus giving Malodobry a means of applying the skin irritants; and therefore, the combination of methods (Malodobry and Bogart) leads to the invention. The Examiner concludes that such a combination would be obvious to one of ordinary skill in the art because the device/method of Bogart provides a specific method for implementing Malodobry's suggestion of using a sodium chloride irritant to increase wound exudate or drainage. The Examiner further concludes that one of ordinary skill in the art would recognize that the device/method of Bogart would especially enable the exudate to carry the pigments as intended by Malodobry because Bogart teaches his method would cause exudate to sweep bacteria to the outer layer and bacteria are as large or are larger than the pigment agglomerates.

Applicants respectfully disagree. The fact that one step, *i.e.* removing pigments from a pigmented section of skin, of an invention is disclosed in one reference (Malodobry) and another

step, *i.e.* applying a salt-based gel to a wound, in a second reference (Bogart) does not, in and of itself, render the claimed invention an obvious combination of the two references. In other words, a simple teaching of elements/steps is insufficient to establish *prima facie* obviousness. The prior art must suggest the desirability of the claimed invention and/or give some reason why one of ordinary skill in the art would think to combine the references.

*“Obviousness can be established by combining or modifying teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so.”* In re Kahn, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006); MPEP 2143.01 I.

*“The question under 35 U.S.C. 103 is not merely what the references expressly teach but what they would have suggested to one of ordinary skill in the art at the time that the invention was made.”* In re Lamberti, 545 F.2d at 750, 192 USPQ at 280 CCPA 1976.

Therefore, in order for an Examiner to properly establish a *prima facie* case of obviousness, the Examiner must not only show that all elements of the claimed invention are known or suggested in the prior art, but must also show that one of ordinary skill in the art would have some reason or motivation to put all the elements together to achieve the claimed invention.

As noted above, the claimed invention is a method for removing pigments from a pigmented section of skin by destroying pigment-containing cells to liberate the pigments/cellular fluids and applying a material, *i.e.* a salt-based granular paste, to the punctured skin which accelerates the migration of the pigments/cellular fluids to the surface of the skin where they (pigments/cellular fluid) are absorbed by a pad and thus quickly removed. This method is not suggested by the combined teachings of Malodobry and Bogart nor is there any reasonable basis for suggestion or motivation to combine the teachings in the first place.

The unequivocal purpose of Bogart is to provide gels which promote the healing of wounds. See abstract; column 1, lines 5-10; column 7, lines 55-68; and Example 2. In contrast, Malodobry (and the claimed invention) aim to irritate and/or encourage inflammation/infection of a wound to expedite elimination of mechanically-destroyed pigments. See paragraphs [0041]; [0045]-[0047]; and [0050]-[0052] of Malodobry and paragraphs [0014]; [0027]; [0029]; and [0034] of the published application. Since encouraging a wound to heal is an opposite action

than encouraging inflammation by irritating a wound, there is no reasonable basis for concluding that one of ordinary skill in the art would turn to the teachings of Bogart if one happened to be looking for a way to implement Malodobry's suggested irritant application. For example, if one were to conduct an electronic data base search, Bogart would be disregarded on the base of the abstract alone, which begins with "Therapeutic gels are provided which promote the healing of wounds..." Emphasis added herein by Applicants. Thus, rather than turning to the teachings of Bogart, it is much more likely that an artisan of ordinary skill would consider Bogart irrelevant.

It is additionally important to note that Bogart's gel is designed to remain on a wound for an extended period of time and thus has "staying power." The specific viscosity and yield point (of the gel) enable the gel to flow into and conform to the interstices of a wound and remain in place regardless of gravity or movement of the patient. Since the gel is self-adhesive, it does not require any padding and/or dressing.

Bogart's gel has the "...*unique ability to both conform to the interstices of a wound and to remain in the wound and not flow out of it when the patient moves. Because of this ability, the gel can be applied directly to the wound site and allowed to remain in place uncovered...*" See column 3, lines 38-42.

Bogart's gels having a "...*specified maximum viscosity and the minimum yield point...flow easily into the convolutions of a wound, even one as deeply embedded as the Stage 3 wound shown in FIG. 2, and stay there, notwithstanding movement of the patient or the force of gravity.*" See column 5, lines 15-20 and Figure 2.

Considering the characteristics of Bogart's gel, the implications are clear. If one punctured an area of skin according to the method of Malodobry and subsequently applied the gel of Bogart to the punctured skin, the gel would flow into the holes made by the needle and thus prevent or hinder the upward flow of pigments and cellular fluids towards the surface of the skin. One would not be able to remove pigments quickly and certainly not in period of twenty minutes or less as is done in the claimed method. Additionally, Malodobry relies on the body's natural processes for removal of pigments further implying a slow process. See paragraphs

[0048]-[0049]. Thus, in contrast to the Examiner's conclusion, this combination does not result with the method as currently claimed because migration of pigments is not accelerated.

Furthermore, it is important to emphasize that Bogart's gel has "staying power." For example, the gel is disclosed as remaining in place for 4-8 hours (Example 2A) or a day (Example 2C). Malodobry makes no mention of how one would go about applying gels/pads. The pad used in the claimed method is applied, absorbs pigments/fluids, and is removed in approximately twenty minutes or less (paragraph [0029]), thus exemplifying another way in which the combination of Malodobry and Bogart does not produce the method as currently claimed (length of time applied to the wound).

Bogart states that his gels are effective for drawing exudates, bacteria, and infection away from a wound. *See* column 4, lines 57-64 and column 8, lines 1-11. However, there is no evidence that these gels, if applied to the skin after the skin has been punctured according to the method of Malodobry, would be capable of "accelerating a process of migration of pigments toward an outer layer of skin" which is a required characteristic of the claimed method. The evidence actually leads away from this teaching. As noted above, Bogart's gel would flow into and remain in the holes created by the needles. This "filling of the holes" impairs the upward flow and absorption of the pigments/fluids.

From Bogart's assertion that his gels draw exudates, bacteria, and infection away from the wound, the Examiner construes that since Bogart's gels would cause bacteria to be swept from a wound these gels would also cause pigments/pigment agglomerates to be swept from a wound because bacteria are as large or are larger than the pigment/pigment agglomerates.

Applicants respectfully disagree. Bacteria are actually much smaller than the ink pigments of a tattoo. In order to verify the correctness of this statement, the Applicants arranged for a series of experiments to be carried out to measure the average size and weight of the ink pigments used for creating tattoos.

The experimental procedure and results are described in detail in the attached Declaration under 37 C.F.R. §1.132 signed by Sylvia Berman, MSc. There is no relationship between Applicants and Sylvia Berman. She is not an employee of the Applicants and she has no

financial interest in the invention described in the instant application. She was asked only to perform the experiments to measure the approximate average dimension and weight of granules of tattoo ink pigments and to compare the findings with the known average dimension and weight of typical bacteria.

The average bacterium (*i.e. E. Coli*) is known to have a dimension on the order of 0.5-5 microns and a weight of  $0.665 \times 10^{-12}$ . The pigment crystals were found to have a mean square area of  $136.6 \pm 64.3$  microns. It is important to note that this measurement represents a single crystal, pigment agglomerates are much larger. The average weight of an agglomerate of crystals was found to be  $2 \times 10^{-7}$  µg, a weight on the order of  $10^5$  heavier than a bacterium.

Even if one assumes that Bogart's gel would be capable of causing bacteria to migrate through needle holes created by Malodobry's method to the surface of the skin and even if one also assumed that the rate of migration of the bacteria would take place at a rate comparable to the rate at which the pigment agglomerates move to the surface using the claimed method, it can not be concluded that the rate at which Bogart's gel would cause pigment agglomerates to move to the surface (of the skin) is comparable to the rate at which it causes bacteria to move to the surface (of the skin). Since there is a large difference in size and weight between the pigment agglomerates and bacteria it is clear that the viscous forces will be much greater in the case of the pigment agglomerates and they (the agglomerates) would migrate much more slowly, if at all, through Bogart's gel present in the needle holes.

Another reason that leads one to the conclusion that upward movement of pigments using the gel of Bogart in the method of Malodobry would be slower than upward movement using the claimed method is connected to the hygroscopic forces exerted by the salt-based granular gel on the cellular fluids. According to the method of the invention (see previous Declaration under 37 C.F.R. §1.132 filed on September 16, 2009), the pigments are drawn to the surface by the hygroscopic forces exerted on the intracellular fluid by the high salt concentration in the granular paste. In the claimed method, the granular paste is found on the skin surface at the opening of the holes created by the needles thereby maximizing the hygroscopic force exerted. In Bogart, the gel is found inside the holes and therefore at least a portion of the total hygroscopic force

would not be directed toward the skin surface. Thus, for the same concentration of salt, the granular paste of the claimed invention would be more effective at causing the pigments to move towards the surface of the skin than would the gel of Bogart. This is yet another way in which the combination of Malodobry and Bogart does not produce the method as currently claimed.

The addition of Garitano adds nothing to the combination of Malodobry and Bogart.

Garitano unquestionably teaches needleless administration of tattoo ink. See abstract and paragraphs [0001] and [0006]. Furthermore, his method was designed specifically to circumvent the disadvantages of needles. See paragraphs [0002]-[0005]. Thus, it is highly unlikely that a skilled artisan would consider the teachings of Garitano as applicable to Malodobry or any other method or device requiring needles for puncturing the skin.

In summary, it is clear that one of ordinary skill in the art would have no reason or motivation to combine any of the teachings of Malodobry, Bogart, and Garitano and thus Applicants respectfully submit that the grounds presented by the Examiner are insufficient to support a *prima facie* case of obviousness. Specifically:

i. The Examiner has not shown any support for his assumption that one of ordinary skill in the art would employ the therapeutic gels of Bogart, gels which promote the healing of wounds, to implement Malodobry's suggestion of encouraging infection/inflammation by irritating the wound. Applicants contend that such a combination would never be considered by one of ordinary skill in the art.

ii. Bogart's gel would flow into and remain in the holes created by the needles (as in the method of Malodobry), thereby at best hindering the upward movement of the pigments and at worst possibly totally blocking movement.

iii. The Examiner has based part of his rejection on the assumption that bacteria are as large as or are larger than tattoo ink pigment agglomerates. Thus, assuming that Bogart's gel can cause the exudates to sweep bacteria to the surface of the skin, the Examiner concludes that the gel can do the same for the pigments/pigment agglomerates. Applicants have supplied experimental evidence via the attached Declaration to show that this conclusion is not viable considering that bacteria are actually much smaller than pigment agglomerates found in tattoo

inks.

iv. The basic physical phenomena that causes the pigments/pigment agglomerates to move toward the surface of the skin relied on when carrying out the claimed method, *i.e.* hygroscopic force, at least partially works against upward motion if using Bogart's gel because of the presence of the gel within the holes created by the needles.

As evident by all of the above arguments, neither the cited references (Malodobry, Bogart, and Garitano) nor any other prior art describe or suggest a method for removing pigments from a pigmented section of skin as is currently claimed in independent claims 1 and 28.

Accordingly, Applicants respectfully submit that independent claims 1 and 28 are patentable over Malodobry in view of Bogart or Malodobry in view of Bogart and Garitano. As claims 2-7, 9, 14-24, and 27 depend on claim 1, these dependent claims necessarily include all the elements of their base claim. Thus, Applicants respectfully submit that the dependent claims are allowable over Malodobry in view of Bogart or Malodobry in view of Bogart and Garitano for at least the same reasons.

In light of the foregoing arguments and those presented in the previous Responses, Applicants respectfully request reconsideration and withdrawal of these rejections under 35 U.S.C. §103(a).

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## **Conclusion**

In light of the foregoing amendments, remarks, and Declarations under 37 C.F.R. §1.132 (both the currently- and previously-filed Declarations) this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

The fee for a three-month extension of time pursuant to 37 CFR §1.17(a)(3) in the amount of \$555 is believed to be due and is being paid via credit card. No other fees are believed to be due at this time. However, please charge any other required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 7640-X05-045).

Respectfully submitted,

/Katharine F. Davis Wong/

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